

22. [AMENDED] A method for eliminating or reducing syneresis in a pharmaceutical hydrogel formulation comprised of (a) a therapeutically effective amount of a drug in (b) a hydrogel comprised of water and polyvinyl alcohol having an average viscosity molecular weight between approximately 10,000 and 400,000, wherein the polyvinyl alcohol has a predetermined degree of hydrolysis D_h between approximately 95% and 99% and represents Y percent by weight in a range of approximately 10 wt. % to 30 wt % of the hydrogel, the method comprising

- a1
- a. selecting Y and D_h to correspond to each other such that if D_h is greater than approximately 97.5% then Y is greater than or equal to approximately $5D_h - 479$ or if D_h is less than approximately 97.5% then Y is greater than or equal to approximately $4.16D_h - 385$;
 - b. preparing a solution of polyvinyl alcohol having the parameters selected from step a.
 - c. subjecting said solution to at least a single-cycle freeze-thaw procedure if D_h is greater than approximately 97.5% or subjecting said solution to a multi-cycle freeze-thaw procedure if D_h is less than approximately 97.5%

[in a manner] which provides for a stable hydrogel and reduces or eliminates syneresis upon storage of the formulation for at least six months at a storage temperature in the range of approximately 5°C to 40°C.

a2

23. [Amended] The method of claim 22[23], wherein D_h is in the range of approximately 96% to 99% and Y is in the range of approximately 12 wt. % to 25 wt %.

a3

24. [Amended] The method of claim 22 [28] wherein the polyvinyl alcohol has a viscosity average molecular weight in the range of approximately 12,000 to 200,000.

Please add two new claims.

Rule 12e 31 A method for eliminating or reducing syneresis in a pharmaceutical hydrogel formulation comprised of (a) a therapeutically effective amount of a drug in (b) a hydrogel comprised of water and polyvinyl alcohol having an average viscosity molecular weight between approximately 10,000 and 400,000, wherein the polyvinyl alcohol has a predetermined degree of hydrolysis D_h between approximately 95% and 99% and represents Y percent by weight in a range of approximately 10 wt. % to 30 wt % of the hydrogel, the method comprising

- a. selecting Y and D_h to correspond to each other such that D_h is greater than approximately 97.5% and Y is greater than or equal to approximately $5D_h - 479$;
- b. preparing a solution of polyvinyl alcohol having the parameters selected from step a.
- c. subjecting said solution to at least a single-cycle freeze-thaw procedure,
- which provides for a stable hydrogel and reduces or eliminates syneresis upon storage of the formulation for at least six months at a storage temperature in the range of approximately 5°C to 40°C.

407 32 A method for eliminating or reducing syneresis in a pharmaceutical hydrogel formulation comprised of (a) a therapeutically effective amount of a drug in (b) a hydrogel comprised of water and polyvinyl alcohol having an average viscosity molecular weight between approximately 10,000 and 400,000, wherein the polyvinyl alcohol has a predetermined degree of hydrolysis D_h between approximately 95% and 99% and represents Y percent by weight in a range of approximately 10 wt. % to 30 wt % of the hydrogel, the method comprising